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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,890	09/05/2003	Toshiteru Komatsu	242292US0	6629

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EXAMINER

SINGH, SATYENDRA K

ART UNIT PAPER NUMBER

1651

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/654,890

Applicant(s)

KOMATSU ET AL.

Examiner

Satyendra K. Singh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09/05/2003 12/5/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

S.O.O.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Balcao et al [AX] (see IDS filed on 09/05/2003) and supported by JP 05-137574 [AO] (IDS, supra).

Claims are drawn to “a **method for regenerating an immobilized enzyme for lipolysis** which exhibits a reduced activity after having been used for lipolysis, which comprises the steps of a) **washing the immobilized enzyme comprising fatty acids with a solvent**; b) **controlling an equilibrium concentration** of the fatty acids in the solvent; c) **removing the washed immobilized enzyme** therefrom, and d) **contacting the resulting immobilized enzyme with a fresh enzyme**, wherein the fresh enzyme adsorbs onto the immobilized enzyme; and wherein the **solvent** is selected from the group consisting of **ethanol, n-hexane, and mixtures thereof**”.

Balcao et al [AX] teach a method of regenerating an immobilized enzyme (a lipase) for lipolysis which exhibits a reduced activity after having been used for lipolysis, wherein the spent enzyme is removed and replaced with fresh lipase (see page 413, second paragraph, in particular), wherein the fresh enzyme adsorbs onto the

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immobilized enzyme (step d; see page 408, in particular). It is to be noted that the claimed aspect of **adsorption of fresh enzyme onto the immobilized enzyme** (and onto the free support/matrix used) for regeneration purposes (instant claim 1, step-d) is inherent to the process of immobilization and has been taught explicitly by the prior art (see page 408, second and third paragraph, in particular). Balcao et al [AX] also teach the use of solvents such as ethanol and hexane (cited in claim 3) during the cleaning and regeneration step (see page 413, second paragraph, in particular).

Balcao et al [AX] do not explicitly outline the steps involved in the cleaning and regeneration of the spent immobilized lipase such as washing the immobilized enzyme with a solvent containing fatty acids, and controlling an equilibrium concentration of the fatty acids in the solvent, and removing the washed immobilized enzyme therefrom.

However, JP 05-137574 [AO] teaches in a method of reactivation of immobilized lipase that cleaning and regeneration of the immobilized enzyme include the steps of: washing the immobilized enzyme with a processing liquid consisting of a polar and a non-polar solvent such as ethanol and hexane, and removing the washed immobilized enzyme (see abstract, claims and detailed description, paragraphs 0006 and 0012, in particular) therefrom. The step of (instant claim 1, b) controlling the concentration of the fatty acids in the solvent is inherently met any time the solvent in any concentration is administered to the column because any concentration of solvent will be considered to control the equilibrium due to the inherent relationship between the concentration of solvent and the amount of fatty acids that can be solubilized therein (see prior art [AO], detailed description, paragraph 0010-0012, in particular);

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Thus the teachings of JP 05-137574 [AO] show that the claimed method steps (a, b and c, supra) not explicitly taught by Balcao et al [AX] are in fact inherent in the cleaning and regeneration step taught by the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balcao et al [AX] as applied to claim 1 above, and further in view of JP 05-137574 [AO] and JP 11-075834 [AQ] (prior art documents filed with IDS).

Claims are drawn to "a method for regenerating an immobilized enzyme for lipolysis which exhibits a reduced activity after having been used for lipolysis, which comprises the steps of:

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- a) washing the immobilized enzyme comprising fatty acids with a solvent,
 - b) controlling an equilibrium concentration of the fatty acids in the solvent,
 - c) removing the washed immobilized enzyme therefrom, and
 - d) contacting the resulting immobilized enzyme with a fresh enzyme, wherein the fresh enzyme adsorbs onto the immobilized enzyme; and
- wherein the equilibrium concentration of the fatty acids in the washing liquid is adjusted to fall within the range of from about 4 to 28 wt.%; and
 - wherein the solvent is selected from the group consisting of ethanol, n-hexane, and mixtures thereof".

Balcao et al [AX] teach in general, a method for regenerating an immobilized enzyme for lipolysis which exhibits reduced activity after having been used for lipolysis (see prior art [AX], page 413, second paragraph, in particular); a method of use of solvent such as ethanol and hexane to remove the spent enzyme during cleaning and regeneration, and a method to remove and replace the spent lipase used in the process of lipolysis with fresh enzyme in order to be reused cheaply and effectively on an industrial scale (see prior art [AX], page 413, second paragraph, in particular). Balcao et al [AX] also teach the aspect of contacting the resulting immobilized enzyme (after cleaning step) with a fresh enzyme for regeneration, wherein the fresh enzyme adsorbs onto the immobilized enzyme (see prior art [AX], page 408, second and third paragraphs, in particular).

Balcao et al [AX] inherently teach the steps involved in the cleaning and regeneration of the spent immobilized lipase such as washing the immobilized enzyme

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with a solvent containing fatty acids, and removing the washed immobilized enzyme therefrom (using procedures such as filtration, see instant specification, page 7, in particular) as discussed supra, however, controlling an equilibrium concentration of the fatty acids (see instant claim 2) in the solvent to about 4 to 28 wt.% achieved by varying the ratio of solvent verses the immobilized enzyme within the range of 3 to 20 times (as described in the instant application, see page 7, first paragraph, in particular) is not explicitly disclosed.

The prior art documents JP 05-137574 [AO] (IDS) and JP 11-075834 [AQ] (IDS) each teach the specific steps involved in the method for regenerating spent lipase used in the process of lipolysis using solvents such as ethanol and hexane, including washing the immobilized enzyme and controlling the concentration of the fatty acids in the washing liquid. Controlling the fatty acid concentration is achieved by increasing the solvent amounts used by 1 to 5 times the immobilized lipase (see prior art [AQ], detailed description, paragraph 0012, in particular), and removing the washed immobilized enzyme therefrom by similar procedures (see [AO], paragraph 0016, in particular). The claimed limitation of achieving equilibrium concentration of fatty acids in solvent from about 4 to 28 wt.% is accomplished by increasing the amount of solvent to 3 to 20 times the amount of immobilized lipase (see instant specification, page 7, first paragraph, in particular).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to vary the ratio of the amounts of solvent used over the amount of

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immobilized lipase being regenerated in order to achieve optimum regeneration efficiency and activity of the immobilized lipase for further applications or reuse.

The person of ordinary skill in the art would have been motivated to make that modification because the prior art documents [AO] and [AX] disclose the benefit of optimizing the amounts of solvent used over the amount of immobilized lipase (and thus to control the concentration of fatty acids in the solvent) in order to recover the optimal activity of the lipase (see prior art [AO], paragraph 0015, in particular) in an efficient and cost effective manner, so as to be industrially applicable (see prior art [AX], page 413, in particular). One of ordinary skill in the art would have had a reasonable expectation of success when varying the ratio of solvent to the immobilized enzyme because such optimizations are routine and have been known in the art to significantly effect the recovery of the activity of used immobilized enzymes, including the lipase such as claimed. Thus the invention as a whole would have been *prima facie* obvious to one skill in the art at the time the claimed invention was made.

Conclusion

No claims are allowed. No claims are free of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF.

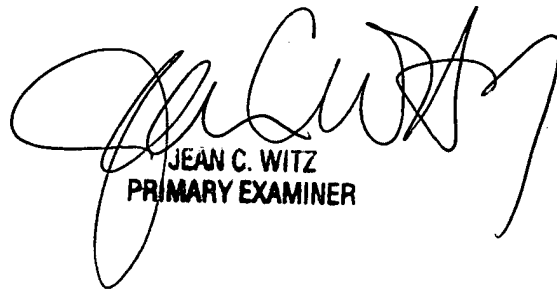
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Satyendra K. Singh



JEAN C. WITZ
PRIMARY EXAMINER